DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-831/S005

Novartis Pharmaceutical Corporation
One Health Plaza
East Hanover, New Jersey 07936-1080

Attention: Ann Shea
Associate Director, Drug Regulatory Affairs

Dear Ms. Shea:

Please refer to your supplemental new drug application dated August 19, 2002, received August 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Foradil Aerolizer (formoterol fumarate) Inhalation Powder.

We acknowledge receipt of your submissions dated December 19, 2002, January 13, 2003, April 11, 2003, May 8, and 21, 2003, and June 3, 10, and 23, 2003.

This supplemental new drug application provides for the use of Foradil Aerolizer (formoterol fumarate) Inhalation Powder for the prevention of EIB in children 5 years old and older.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the draft labeling (text for the package insert and patient instructions for use) submitted on June 23, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-831/S-005." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Pulmonary and Allergy Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Akilah Green, Regulatory Project Manager, at (301) 827-5580.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury
6/27/03 04:39:48 PM